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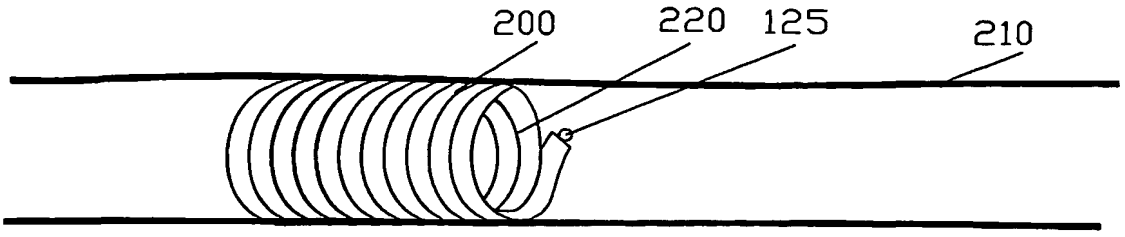
(54) Title: MEDICAL DEVICE HAVING AN UNRAVELABLE PORTION



(57) Abstract: A medical device, such as a stent, having a hollow portion formed from a fashioned filament (100, 110). Between adjacent segments of the fashioned filament is a detachable seam (140). After implantation of the device in the body, the device may subsequently be removed by grasping an end of the filament and pulling the end of the filament so as to detach the seam between adjacent segments of the fashioned filament, and unravel the hollow portion.

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MEDICAL DEVICE HAVING AN UNRAVABLE PORTION

FIELD OF THE INVENTION

This invention relates to medical devices, and more particularly to such devices having a hollow portion such as stents and catheters.

BACKGROUND OF THE INVENTION

Many indwelling medical devices have a hollow portion. For example, stents are hollow devices that are inserted into body ducts for preventing narrowing of the duct lumen, for tutoring a dilated lumen or for acting as a substrate for tissue growth. As another example, a catheter may have a hollow portion that may serve to transfer a fluid from outside the body to a body cavity, or for draining fluid from a body cavity. As yet another example, an artificial blood vessel valve has a casing enclosing a space through which blood flows.

The hollow portion of a medical device may have a fixed caliber in which it is both delivered and deployed. Alternatively, the hollow portion may be brought into an initial, small caliber, conformation in which it is inserted into the body and delivered to the site where it is to be deployed. This allows the hollow portion to be delivered with minimal damage to surrounding tissues. Deployment of the device involves expanding the hollow portion to a final larger caliber. When it is desired to remove the device from the body, the hollow portion may first be made to return to the small caliber conformation and then removed. For example, U.S. Patent No. 5,037,427 discloses a stent made from a two-way shape memory alloy. This stent has a transition temperature that is below body temperature in which it changes its diameter from a narrow diameter to a wide diameter. The stent is inserted into the body under a constant flow of cold fluid in order to maintain the stent in the narrow

diameter during delivery. Once in the stent has been positioned in the desired location, the flow of the cold fluid is stopped and the stent then expands either spontaneously as it warms up to body temperature or by flowing a warm fluid around the stent. When the stent is to be removed, a flow of cold fluid is again applied to the stent causing the stent to soften and return to the narrow diameter conformation. The flow of cold fluid is maintained until the stent is removed from the body.

SUMMARY OF THE INVENTION

The present invention provides a medical device having a hollow portion such as a stent, catheter, filter or valve. In accordance with the invention, the hollow portion is formed from a flexible filament. The filament is fashioned into the shape of the hollow portion of the device. For example, if the hollow portion is a stent or the hollow shaft of a catheter, the filament may be fashioned into a helix. An end of the filament is configured so as to be graspable by a grasping device. Segments of the filament that are adjacent to each other after fashioning are attached to one another by means of a detachable seam. During delivery and deployment of the device, and while the device is in use, the seams are intact. When the device is to be removed from the body, the end of the filament is grasped by a grasping device, which may be located on the tip of a catheter or an endoscopic device. For example, the end of the filament may be from a magnetizable material, in which case the grasping device may consist of a magnet. Alternatively, a hook may be present at an end of the filament, in which case, the grasping device contains a hook capable of engaging the hook on the filament. The grasping device is withdrawn from the body, pulling the grasped end of the filament along with it. As the grasping device continues to be withdrawn, the continued pulling on the grasped end of the filament causes the seams in the device to split. As the filament continues to be pulled, the hollow portion of the device progressively unravels until the filament becomes essentially linear and is easily removed from the body.

In its first aspect, the invention thus provides a medical device having at least a hollow portion, the hollow portion being formed from a fashioned filament and having a detachable seam between at least one pair of adjacent segments of the fashioned filament.

In its second aspect, the invention provides a method for removing a hollow portion of a medical device from a body, the hollow portion being formed from a fashioned filament and having a detachable seam between adjacent segments of the fashioned filament, comprising:

(a) Grasping an end of the filament;

(b) pulling the end of the filament so as to detach the seam between adjacent segments of the fashioned filament.

In its third aspect, the invention provides a method for forming a hollow portion of a medical device, the hollow portion having a shape comprising the method:

(a) forming a filament into the shape of the device;

(b) forming a seam between at least one pair of adjacent segments of the fashioned filament.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

Fig. 1 shows formation of a filament for use in the construction of a hollow tubular portion of a medical device in accordance with the invention;

Fig. 2 shows the filaments of Fig. 1 after application of a coating;

Fig. 3 shows seams in a hollow portion of an implantable device of the invention;

Fig. 4 shows a hollow portion of a device of the invention after insertion into the body;

Fig. 5 shows removal of the device of Fig. 4 from the body;

Fig. 6 shows formation of a hollow tubular portion of a medical device in accordance with another embodiment of the invention

Fig. 7 shows another embodiment of the invention having a filament fashioned into an undulating helix embedded in a polymeric coat;

Fig. 8 shows schematically a filament fashioned into a helix having a triangular cross-section with bends along its length; and

Fig. 9 shows weakening of the polymeric coat between turns of the helix of the embodiment of Fig. 7.

DETAILED DESCRIPTION OF THE INVENTION

First embodiment

Fig. 1 shows the construction of a hollow portion of a medical device in accordance with the invention. In Figs. 1a, b, and c, a flexible filament **is** fashioned into a desired shape. The filament may be for example a metal wire from stainless steel or a nickel-titanium alloy (Nitinol). In Fig. 1a, the filament **100** has been fashioned into a helix that may be used as a cylindrical hollow portion of a stent, or catheter, or artificial blood vessel valve. Fig. 1b shows an alternative method for fashioning a filament **110** into an essentially cylindrical form that may be used in a stent or catheter. The cylinders shown in Figs. 1a and 1b have a circular cross-section. This is by way of example only, and the filament may be fashioned into a cylinder having any desired cross-sectional shape as required by any particular application. A filament that has been fashioned into a cylinder having a triangular cross-section, as shown in Fig. 1c, or an hourglass cross-section may be used in the construction of a stent for insertion into a tubular body organ having a triangular cross-section or an hourglass cross-section, such as the prostatic urethra. A filament that has been fashioned into a cylinder having a variable diameter, as shown in Fig. 1d, may be used in the construction of an artificial blood vessel valve or filter. Two sub-filaments may joined to form a bifurcating filament, as shown in Figs. 1e and 1f, that may be used in the construction of a bifurcating stent to be used at a bifurcation in a blood vessel. In Fig. 1e, an end of a sub-filament **170** is attached at the middle of a sub-filament **172.** The attachment may be formed, for

example, by welding of the two sub-filaments together at the point of attachment. Alternatively, the attachment of the two sub-filaments may be maintained by a coating of the filament, as described in detail below. In Fig. 1f, two sub-filaments **165** and **166** are fashioned parallel to each other in a non-bifurcated portion **168** of the filament. In the bifurcated portion **169** of the filament, the two sub-filaments separate and are fashioned individually. The shapes and applications shown in Fig. 1 are by way of example only, and the invention provides implantable medical devices having a hollow portion of any shape and dimensions as required in any particular application.

One or more bends may be introduced in the filament in order to facilitate folding of the tubular portion, as described below. Fig. 8 shows, for example, a filament **800** folded into a cylinder having a triangular cross-section having folds **810** periodically arranged along its length. For clarity, the cylinder in Fig. 8 is represented as having been sectioned longitudinally and unrolled onto the plane of the Figure.

After fashioning into the desired shape, an end of the filament is configured to be graspable by a grasping device as explained below. In Fig. 1 a, for example, an end **125** has been fashioned into a planar shape that is graspable by a spring biased clamp located on a grasping device. As another example, in Fig. 1b, and end **130** has a magnetizable portion **132** that may engage a magnetizable portion on a grasping device. As yet another example, in Figs. 1c to 1f, an end **135** of the filament **120** has been fashioned into a hook that may engage a hook on a grasping device.

Once the filament has been fashioned into the desired shape, a polymer suspension is applied to the filament so as to form a thin coating on the filament. The polymer suspension is applied by any known method such as brushing, spraying or immersion of the filament. After applying the polymer solution, the solution is allowed to cure on the filament. Figs. 2a to 2f show the filaments of Figs. 1a to 1f, respectively, after application of the polymer suspension. The cured polymer fills in spaces between adjacent regions of the fashioned filament so as to provide the coated filament with a continuous surface.

Fig. 3 shows, as an example, the filament **100** after application of the polymer solution to produce the hollow portion **160** of an implantable medical device. For better clarity, part of the filament and associated coating has been cut out. The polymer has formed a continuous coating **150** on the filament **100**. The polymer has thus formed seams between regions of the fashioned filament **100** that are adjacent to one another, for example the seam **140** between the regions **145** and **160** of the filament **100**. The polymer coating **150** is selected so that the seams **140** are torn when adjacent regions in the fashioned filament joined by a seam are separated, as explained in detail below. The seam may be weakened to facilitate removal, as described below, by making the thickness of the coating thinner in the seams than it is along the filament or by perforations (not shown) introduced into the seam. The polymer solution may optionally be chosen so that the coated filament is elastic. The polymer solution may be for example a 2:3 solution of silicone rubber and a solvent. This solution may be used when it is desired that the hollow portion be elastic. In this case, the hollow portion may be deformed into a small caliber conformation and maintained in this conformation, for example, by a constraining sleeve. After positioning of the device in the body, the device is deployed by removing the constraint. Due to the elasticity of the hollow portion, the hollow portion then returns to its undeformed conformation.

Fig. 4 shows a device comprising the hollow portion **200** of a medical device formed as above, after deployment in the body. The device may be, for example, a stent, catheter, filter or valve that has been introduced into a body duct **210**, such as a blood vessel.

Fig. 5 shows removal of the hollow portion **200** from the body. In Fig. 5a, a retriever **400** is inserted into the body. At the distal end of the catheter is a grasping device **155** configured to engage the end **125** of the filament **100.** In the example shown in Fig. 5, the end **125** has been fashioned into a planar region, and the grasping device **155** is a spring biased clamp that is configured to grasp the planar region. The spring biased closed **155** clamp is opened by pulling a wire **420** that extends from the clamp **155** to the proximal end **430** of the retriever **400.**

Once the end **125** has been engaged by the grasping means of the retriever **400,** the retriever is withdrawn from the body duct **300,** and the end is pulled away from the device. Since the device is lodged in the body duct, as the retriever **400** is withdrawn and the end is pulled, the seam between adjacent regions of the filament tears, and the coated filament progressively unravels (Fig. 5c). The tearing is facilitated if the polymer coating in the seam is weaker than in regions adjacent to the filament, for example, by scoring the coating along the seam to make the seam thinner than the rest of the coating, or by introducing perforations in the coating along the seam. The filament continues to unravel until the stent is essentially linear (Fig. 5d) and can be removed from the body. In the case of the bifurcated device shown in Fig.2e, as the filament unravels, it assumes a bifurcated or Y shape that is easily removed from the body. In the case of the bifurcated device shown in Fig. 2f, in which the attachment of the two sub-filaments is maintained by the polymer coating, one of the two sub-filaments is first removed causing the polymer coating at the attachment to tear so as to separate the two sub-filaments. The second sub-filament is then removed.

Second Embodiment

Fig. 6 shows the construction of a hollow portion of an implantable medical device in accordance with a second embodiment of the invention. As shown in Fig. 6a, a filament **500** is used having a groove **510** extending longitudinally along one edge of the filament and a ridge **520** also extending longitudinally along the filament. The filament is made from a resiliently flexible material such as rubber. The groove **510** and the ridge **520** are positioned diametrically opposite one another on the filament. The groove **510** and the ridge **520** are shaped so that the ridge **520** on one segment of the filament may be snapped into the groove on another segment of the filament as shown in Fig. 6b. The filament is brought into a desired configuration, for example a helix as shown in Fig. 6c. The ridge **520** of the filament in each turn of the helix is snapped into the groove **510** on an adjacent turn of the helix, to produce a detachable seam along the length of the filament. This

device may be inserted into the body and removed as explained for the previous embodiment.

Third Embodiment

Fig. 7 shows another embodiment **740** of the invention in which a filament **700** has been fashioned into an undulating helix. A removal hook **710** has been formed at an end of the filament **700**. The filament **700** is contained in a polymeric layer **720** such as polyurethane, silicone rubber, or a co-polymer of polyurethane and silicon. The polymeric layer **720** can be made by a dipping process, or by molding extrusion. The polymeric coating **720** is weakened between adjacent turns of the helix (along the curve **730)** in order to facilitate removal as described above for the other embodiments. After the device **740** is deployed in the body, it may be removed by pulling on the removal hook **710**, as explained above in reference to Fig. 5. In this case, the polymeric coating forms a strip containing the undulating helical filament **720**.

Any method may be used to achieve weakening of the polymeric coating along the curve **730.** For example, as shown in Fig. 9a, a narrow helical strip is cut out of the polymeric material **720** along the curve **730,** and a weaker external polymeric coat **900** is applied to the device **740** that also replaces the removed material. Figs. 9b and 9c show weakening the polymeric coat **720** by introducing perforations **910** along the curve **730.** The perforations are shown en face in Fig. 9b and in cross-section in Fig. 9c. The perforations **910** may be blind perforations formed as shown in Fig. 9c, or may extend through the entire thickness of the polymeric layer **720.** Figs. 9d and 9e show another method for weakening the polymeric coat **720** in which a groove **930** is routed in the polymeric coat **720** along the curve **730.** . The groove **910** is shown en face in Fig. 9d and in cross-section in Fig. 9e. Fig. 9f shows yet another method for weakening the polymeric coat **720** in which a cut **920** is made along the curve **730** without removing any of the polymeric material **720,** and a weaker external polymeric coat **940** is applied to the device **740.**

CLAIMS:

1. A medical device having at least a hollow portion, the hollow portion being formed from a fashioned filament and having a detachable seam between at least one pair of adjacent segments of the fashioned filament.

2. The medical device according to Claim 1 wherein the seam is formed by a polymeric material joining adjacent segments in the fashioned filament.

3. The medical device according to Claim 1 wherein a groove extends along a first edge of the filament and a ridge extends along a second edge of the filament, the seam being formed by snapping the ridge in a first segment of the filament into the groove in an adjacent segment of the fashioned filament.

4. The medical device according to any one of Claims 1 to 3 having a hook at an end of the filament.

5. The medical device according to Claim 1 having a magnetzible portion at an end of the filament.

6. The medical device according to Claim 1 being a stent, a catheter or an artificial blood vessel valve.

7. The medical device according to any one of the previous claims wherein the hollow portion has a circular, triangular or hourglass cross-section.

8. The medical device according to any one of the previous claims in which the hollow portion is bifurcated.

9. The medical device according to Claim 2 wherein the coating is perforated in the seams.

10. The medical device according to Claim 2 wherein the seam is formed by cutting the polymeric material and applying an outer polymeric coat to the device.

11. The medical device according to Claim 2 wherein the coating has a thickness in a portion of the seams that is less than the thickness adjacent to the filament.

12. The medical device according to Claim 1 wherein the filament has bends along its length.

13. A system comprising:

(a) A medical device formed from a fashioned filament and having a detachable seam between at least one pair of adjacent segments of the fashioned filament.

(b) A retrieving device having a grasping device configured to grasp an end of the filament.

14. The system according to Claim 13 wherein the medical device has a magnetizable portion at the end of the filament and the grasping device includes a magnetizable portion.

15. The system according to Claim 13 wherein the medical device has a hook at the end of the filament and the grasping device includes a hook.

16. The system according to Claim 13 wherein the grasping device includes a spring biased clamp configured to grasp the end of the filament.

17. The system according to any one of Claims 13 to 16 wherein the hollow portion has a circular or triangular cross-section.

18. The system according to any one of the Claims 13 to 16 wherein the hollow portion is bifurcated.

19. A method for removing a hollow portion of a medical device from a body, the hollow portion being formed from a fashioned filament and having a detachable seam between adjacent segments of the fashioned filament, comprising:

(c) Grasping an end of the filament;

(d) pulling the end of the filament so as to detach the seam between adjacent segments of the fashioned filament.

20. A method for forming a hollow portion of a medical device, the hollow portion having a shape comprising the method:

(c) forming a filament into the shape of the device;

(d) forming a seam between at least one pair of adjacent segments of the fashioned filament.

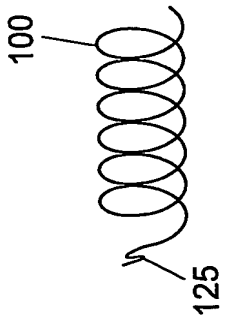

FIG. 1A

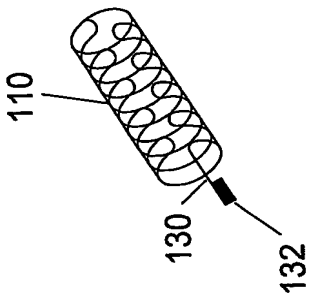

FIG. 1B

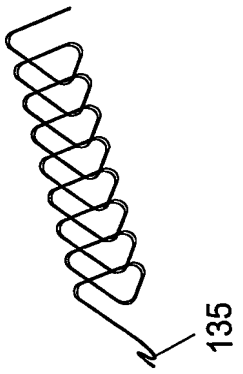

FIG. 1C

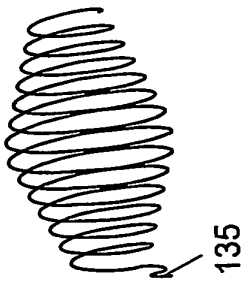

FIG. 1D

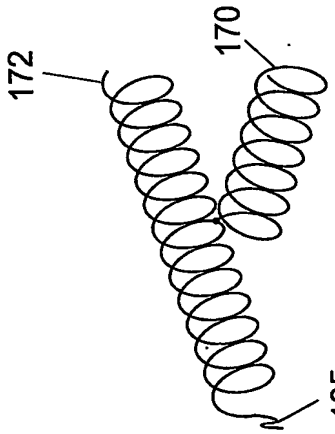

FIG. 1E

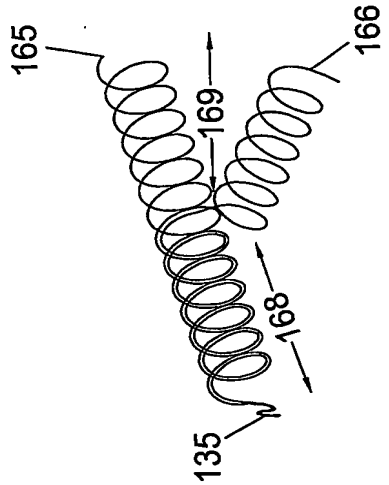

FIG. 1F

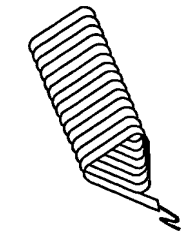

FIG. 2C

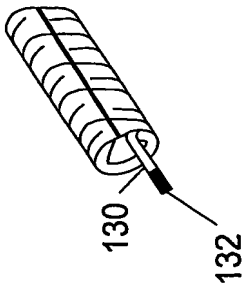

FIG. 2B

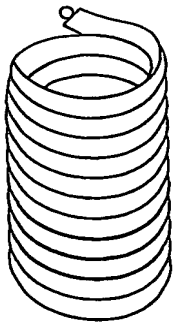

FIG. 2A

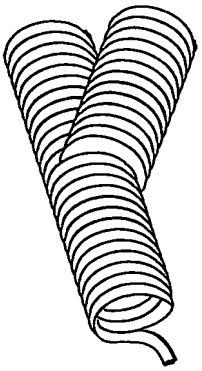

FIG. 2F

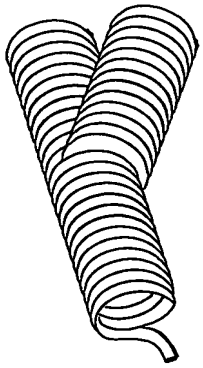

FIG. 2E

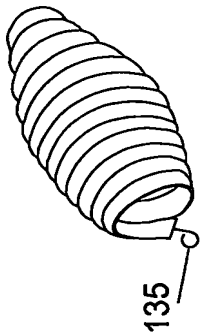

FIG. 2D

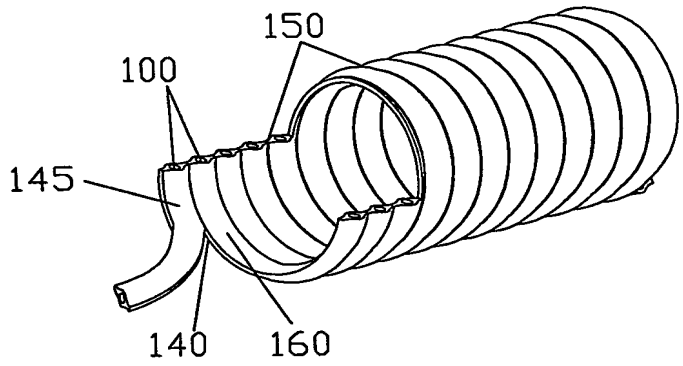

FIG. 3

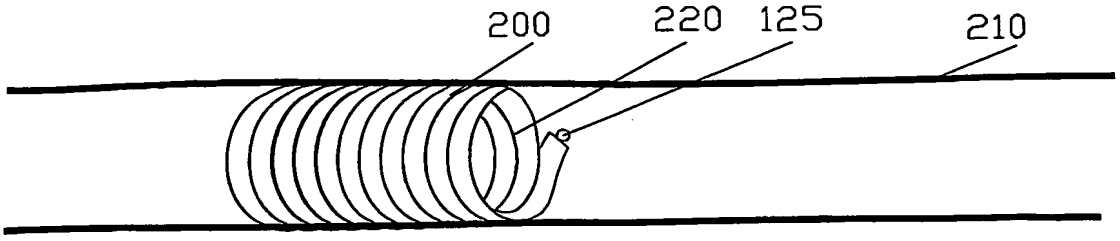

FIG. 4

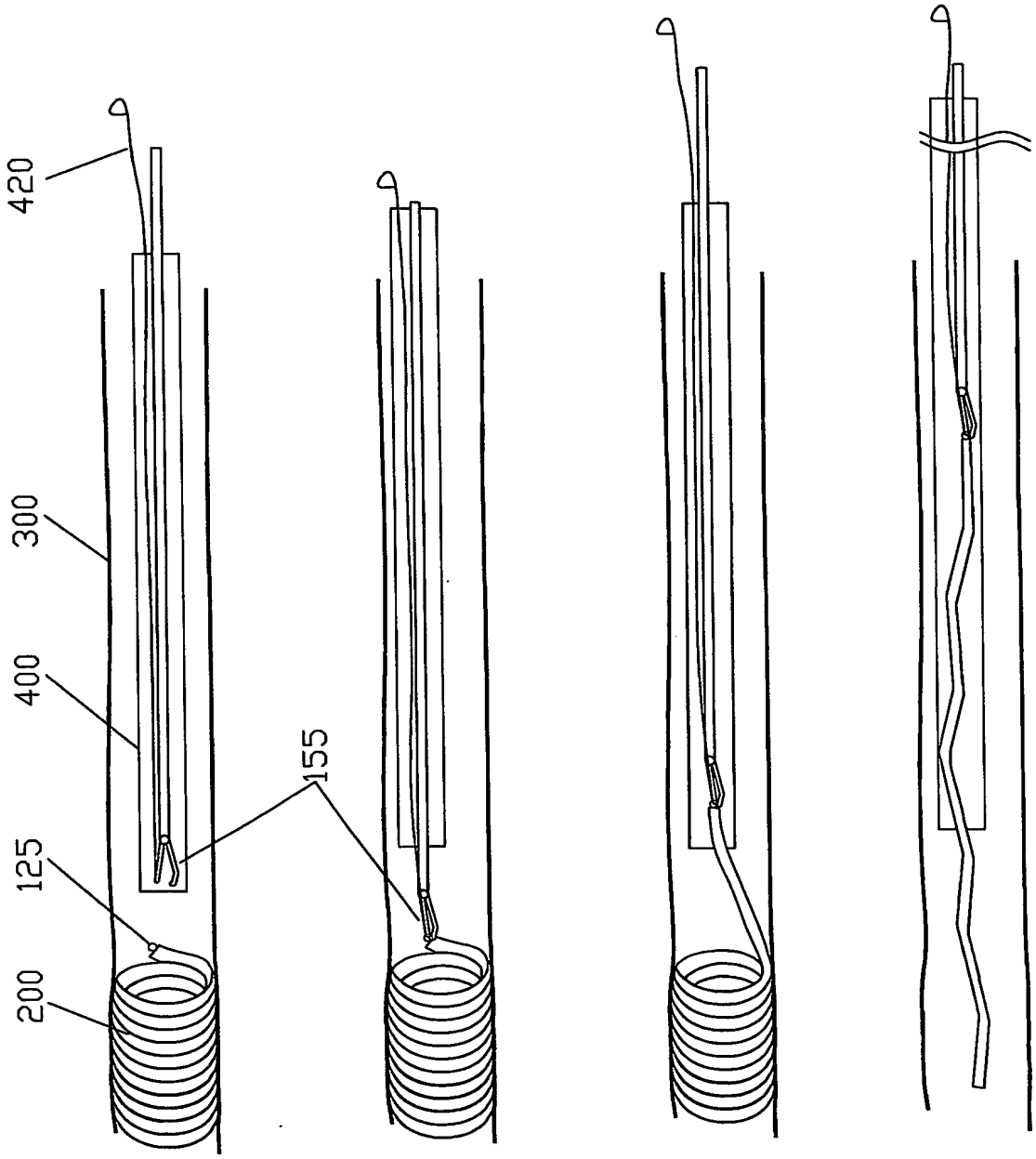

FIG. 5A FIG. 5B FIG. 5C FIG. 5D

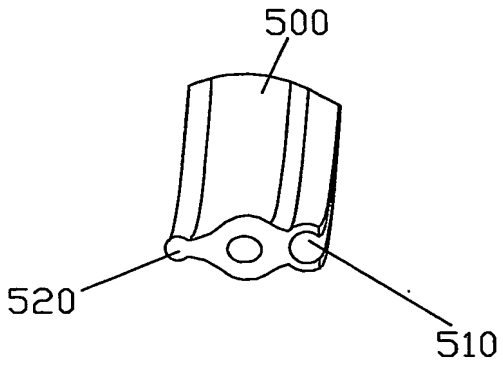

FIG. 6A

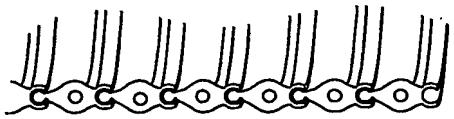

FIG. 6B

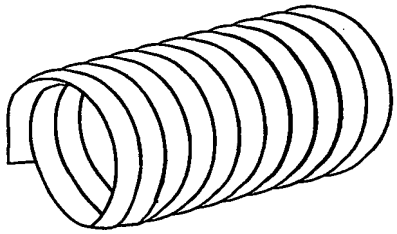

FIG. 6C

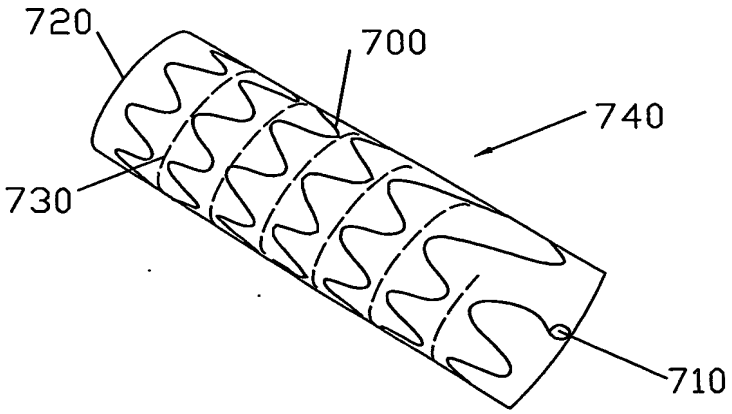

FIG. 7

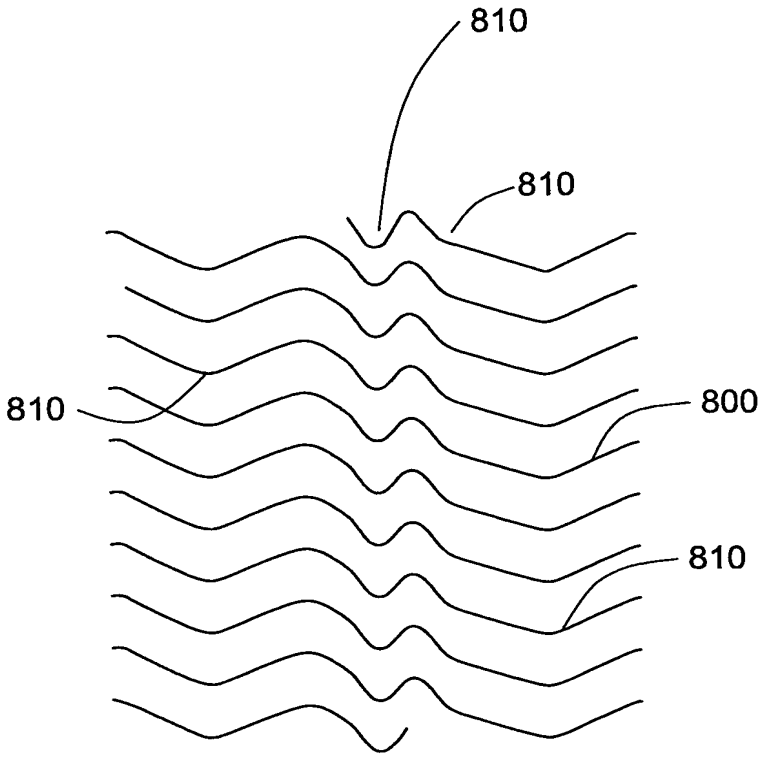

FIG. 8

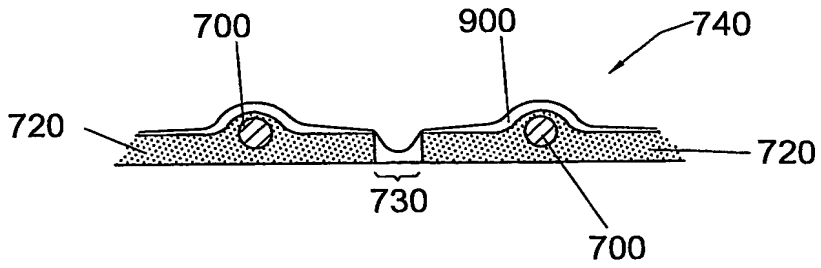

FIG. 9A

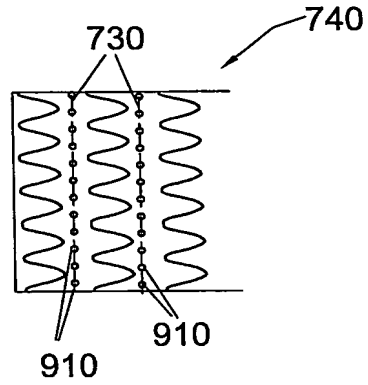

FIG. 9B

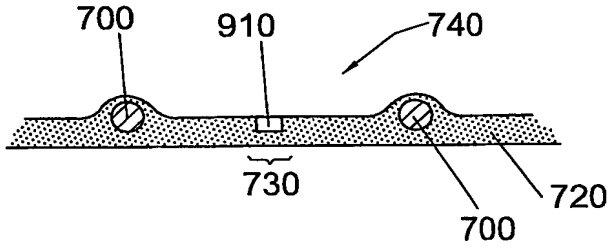

FIG. 9C

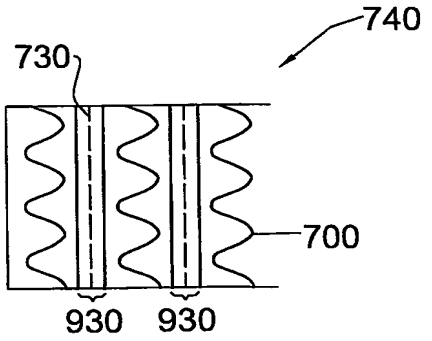

FIG. 9D

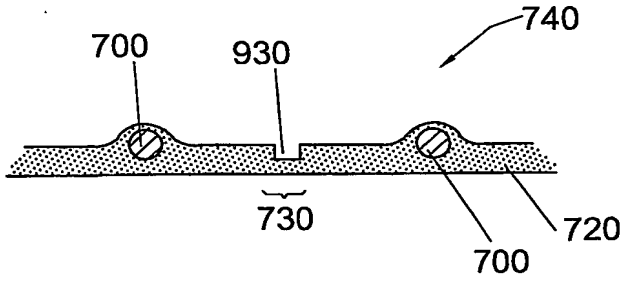

FIG. 9E

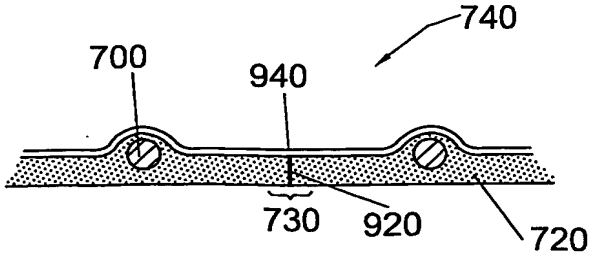

FIG. 9F

INTERNATIONAL SEARCH REPORT

PCT/IL 03/00427

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/040236 A1 (MARONEY CHARLES T ET AL) 4 April 2002 (2002-04-04)	1,6,7,12
A	paragraph '0085! - paragraph '0091! paragraph '0136! figure 17	13,20
X	EP 1 110 561 A (ETHICON INC) 27 June 2001 (2001-06-27)	20
A	claim 1 figures 3,4	1,19

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 October 2003	20/10/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Amaro, H

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-19

   A system comprising a medical and a retrieving device. The medical device is a hollow portion formed from a fashioned filament and comprises a detachable seam. The retrieving device comprises a grasping device configured to grasp an end of the fashioned filament.

2. Claim : 20

   Method for forming a hollow portion of a medical device

INTERNATIONAL SEARCH REPORT

PCT/IL 03/00427

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/IL 03/00427

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